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| 10/638,426 | 08/12/2003 | Samuel J. Epstein | 12013/47601 | 5077 |

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KENYON & KENYON LLP
1500 K STREET N.W.
SUITE 700
WASHINGTON, DC 20005

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| EXAMINER |
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KOHARSKI, CHRISTOPHER

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| ART UNIT | PAPER NUMBER |
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3763

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06/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/638,426

Applicant(s)

EPSTEIN ET AL.

Examiner

CHRISTOPHER D. KOHARSKI

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8-16, 19, 20 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) 4, 8 -16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 19-20 and 22-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 2/15/2008 in which claims 1 and 19-20 were amended and new claims 22-27 were added. Currently claims 1-4, 8-16, 19, 20 and 22-27 are pending for examination with claims 4, and 8-16 withdrawn from a previous election restriction.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 19-20, 22, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Antanavich et al. (6,132,396). Antanavich et al. discloses an apparatus for applying tissue sealant.

Regarding claims 1-3, 19-20, 22, and 25, Antanavich et al. discloses a device and method for direct delivery of a preloaded (Figure 1) shear thickening fluid (fibrin composition, see arguments below) having therapeutic properties (sealing, wound protection), the device comprising: a channel (near 24) having a proximal (near 22,23) and distal end (25) with a lumen extending therethrough, the channel containing a shear thickening (fibrin composition), the channel configured to expose the fluid to a viscosity adjuster comprising protrusions (26, 29) at the distal end which form a constricted flow

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orifice (near 25) (Figure 4) and causes an increase in the viscosity of the fluid (Figures 1-4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23-24, and 26-27 are rejected under 35 U.S.C 103(a) as being unpatentable over Antanavich et al. (6,132,396) in view of Freyman et al. (US2004/0030282) or Sawhney (USPN6,179,862). Antanavich et al. meets the claim limitations as described above except for the fluid containing a therapeutic substance.

However, Freyman et al. teaches an injection device used to deliver therapeutic agents and Sawhney discloses method and device for in situ formation of hydrogels.

Regarding claims 23-24, and 26-27, Freyman teaches an agent delivery system (Figures 1-2) that discloses a multi-part injection composition consisting of therapeutic drugs ([0023-0024]) and fibrin ([0042]).

Regarding claims 23-24, and 26-27, Sawhney teaches a hydrogel sealant agent delivery system (Figure 1a) that discloses a composition consisting cross-linkable agent in conjunction with therapeutic drugs (col 3, ln 1-10).

At the time of the invention, it would have been obvious to incorporate the therapeutic agents of Freyman or Sawhney to create a drug delivery layer with the tissue sealant. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Freyman ([0005-0008]) or Sawhney (cols 1-2).

Response to Arguments

Applicant's arguments filed 2/15/2008 have been fully considered but they are not persuasive. Applicant's Representative asserts that Antanavich reference does not disclose delivery of a shear-thickening fluid.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the fibrin delivery composition is a shear thickening fluid under the definition provided below and the supported patents (Sierra et al. (USPN5,290,552, Levinson et al. (USPN6,432,084). The Examiner is defining a shear thickening fluid as:

"shear thickening", Fluid Mechanics. Copyright © 1992, 1996 by Academic Press.

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“The phenomenon in which non-Newtonian fluids subjected to shear stress will undergo a viscosity increase; e.g., a dilatant material such as a starch suspension in water.”

As described in each of the patents listed above (Sierra et al. (cols 1-2, col 11); Levinson et al. (cols 3-4, 7) the fibrin composition is a well known multi-polymer solution that contains a liquid part with several small chain polymers in solution and suspension that will react to shear stress in a non-Newtonian way.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests further clarification of the claims including structural/spatial limitations of the velocity adjuster as shown in Applicant's Figures 1-3.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 6/06/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763